

Remarks

Reconsideration of the application is requested. Claims 1, 4-10, 13, 15, 19, 30-33, 35-39, and 41-44 are now in the application. Claims 30, 36, 41 have been amended. Claims 42-44 have been added.

This claims as amended traverse the rejections for the reasons listed below; the rejections are addressed in the order presented in the Office action. The remarks also address comments made in a teleconference with the Examiner on December 17, 2007, that was noted in the interview summary dated December 26, 2007.

Claims 30 and 41 have been amended to the format preferred by the Examiner to avoid a 35 USC § 101 rejection. In the conversation with the Examiner, she provided a preferred wording to avoid confusion regarding positively claiming a part of the body. The preferred wording was language such as “configured to contact [a piece of the body]”. The claims have been amended to reflect this preference. These amendments are not related to prior art.

A substitute declaration is attached. The substitute declaration identified the application by application number and filing date and includes the statement regarding 37 CFR 1.56. Accordingly, the substitute declaration meets the requirements of 37 CFR 1.67(a).

The Examiner makes two rejections under 35 USC § 112 involving the phrase, “Said first surface maintaining an equal distance from said second surface when moving from the wide position to the narrow position.” The undersigned attorney believes that the Examiner’s confusion stems from confusion regarding the intended meaning of the phrase. So, before addressing the rejections formally, a greater description of the intent of the language is being provided. Looking at Figs. 5-7, the phrase is meant to describe that the surfaces 54 and 56 do not move relative to each other to cause the spreading of the bones. Instead of moving, the surfaces remain in their fixed wedge shape as the spacer is inserted into the joint. The degree of spreading is controlled by the amount of insert of a given implant if wedge shaped or relative difference in height versus width if

rotatable. The language was meant to distinguish the invention from prior art that is implanted and then the surfaces are expanded relative to each other post-insert to expand the joint.

With the above understanding in view, the invention according to claims 1, 4-10, 13, 15, 19, 30-32, 35-39, and 41 meet the requirements of 35 USC § 112, first paragraph, because the claims meet the written description requirement. The Examiner rejected the claims as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that, at the time the application was filed, the invention had possession of the claimed invention. Figs. 8-11 show wedges wherein the surfaces 54 and 56 do not move relative to each other when moving from the wide position to the narrow position. Paragraph [0066] of the specification also shows that the inventor had the invention as described at the time of filing.

Claim 1, 4-10, 13, 15, 19, 30-32, 35-39, and 41 are definite under 35 USC § 112, second paragraph, because the following phrase is definite: "Said first surface maintaining an equal distance from said second surface when moving from the wide position to the narrow position." As stated previously, this phrase describes that the surfaces 54 and 56 do not move relative to each other as the joint is spread from the wide position to the narrow position. This can be done by inserting a wedge or rotating an implant with a greater width than height. When read with this understanding, the plain meaning of the claims is definite.

If the Examiner would like to discuss the 112 rejections further or suggest alternative language, she is asked to contact the undersigned attorney by telephone so that the rejections can be quickly remedied.

Claims 1, 8-9, 13, 19, 30-32, 35, 39, and 41 are patentable over Stone '433 in view of Michelson '635 because one with ordinary skill in the art because the prior art does not suggest all of the features of the invention as claimed: namely, "the implant being fixed to only one of the bones."

To summarize the rejections, the Examiner argues nothing in Stone '433 prevents the prior-art device from being used as described in the claims of the instant application.

However, the logic behind the Examiner's rejection can be attacked by looking at the statute of the rejection. To remind the Examiner, a Section 102 rejection was made previously solely based on Stone. In contrast, the outstanding rejection is now a Section 103(a) rejection. Section 103(a) requires that one with ordinary skill in the art must have some suggestion of the desirability of the claimed invention; *see* MPEP § 2143.01.

Stone '433 teaches an osteotomy wedge. An osteotomy device is a wedge inserted to hold a spread incision in a single bone. The purpose of osteotomy devices is to lengthen one side of a bone so that it may provide an aligned stable bone on which to walk. To fasten an osteotomy device to a bone, superior and inferior screws fasten the wedge to one and only one bone. If either of the screws were not used, the superior part of the bone could move relative to the anterior part of the bone; this would lead to a fracture of the bone. To fix only one of the surfaces to an adjacent surface of the bone would thwart the purpose of the osteotomy device: to provide a stable straightened (leg) bone.

One with ordinary skill in the art viewing Stone '433 would not be suggested to make a wedge shape device and attach it to only one of the bones of the joint. *In arguendo*, one might be suggested by Stone '433 to insert a wedge into a joint. However, one with ordinary skill would also be suggested to fix the first surface to the first bone of the joint and the second surface to the second bone of the joint. Nothing in Stone '433 suggests anything but fixing both the superior and inferior surfaces.

Further evidence that there is no suggestion to alter Stone '433 is that to modify Stone '433 as argued by the Examiner '433 to attach to only one surface of the implant would render Stone '433 unsatisfactory for its intended purpose as an osteotomy device. *See* MPEP § 2143.01(V). Because the modification would render the original device unsatisfactory for its original purpose, one with ordinary skill in the art would have no suggestion to modify the prior art as contemplated by the Examiner.

The Examiner also cites Michelson '635. Michelson '635 does not suggest attaching only one surface a respective one of the bones in a joint. Michelson '635 teaches an implant for fusing adjacent vertebrae to each other. That is, Michelson '635 teaches to fix a first surface to one vertebrae and a second surface to a second, adjacent vertebrae. Nothing in Michelson teaches or suggests fastening the implant to only one bone in the joint.

Claim 4-7 are patentable over Stone '433 in view of Michelson '635 and Jefferies '370 for the reasons stated previously and for the further reason that Jefferies does not teach or suggest using demineralized bone powder and collagen on a metal implant.

First, claims 4-7 ultimately depend on claim 30. As discussed previously claim 30 is not obvious in light of Stone '433 in view of Michelson '635 because the prior art does not suggest a device that is attached to only one of the bones of a joint. Likewise, Jefferies '370 does not teach or suggest this claimed feature. Accordingly, claims 4-7 are patentable over the prior art for the same reason as claim 30.

Second, Jefferies '370 does not teach using the material to coat a device like the one described in the instant application. Rather, Jefferies '370 teaches forming a gel in a "sponge-like configuration." Nothing in Jefferies '370 suggests how the composition can be used as a coating for device like one described in the claims. Without this suggestion, the combination of the references is merely a piecemeal combination and improper use of hindsight. For this reason, the invention according to claims 4-7 would not be obvious to one with ordinary skill in the art.

Claims 15 and 36-38 are patentable over Stone '433 in view of Henderson '175 because the references do not teach all of the features of the claims. Specifically, neither teaches a fastener through a first major side surface and a side surface. Claim 36 has been amended to clarify that the side surface spans the first surface and the second surface. Support for the amendment to claim 36 can be found in the specification in paragraphs [0009] [0049] [0068] and Fig. 8. Claims 42-44 have been added to further claim these features.

Amended claim 36 describes a side surface that spans the first surface and the second surface and further describes a fastener that passes through the side surface and the first surface to connect the body to the first bone.

In contrast, Henderson '175 does not describe a side surface through which the fastener passes. Henderson '175 does show two side surfaces (i.e. the bottom horizontal surface in Fig. 8 and the mesh 41). However, the fasteners 48 and 49 do not pass through those surfaces.

Accordingly, Stone '433 in view of Henderson '175 does not teach or suggest all of the features of claims 15, 36-38 and 42-44. Therefore, the prior art fails to make a *prima facie* case of obviousness and the invention is patentable.

Claim 10 is patentable over Stone '433 in view of Zdeblick et al. '909 for the reasons mentioned previously. Specifically, neither invention suggests an implant that is fastened to only one of the bones of a joint. Because Zdeblick et al. '909 does not teach or suggest this feature alone or in combination with the prior art, the invention according to claim 10 is patentable over the prior art.

In view of the foregoing, reconsideration and allowance of claims 1, 4-10, 13, 15, 19, 30-33, 35-39, and 41-44 are solicited. In the event the Examiner should still find any of the claims to be unpatentable, please telephone counsel so that patentable language can be substituted. In the alternative, the entry of the amendment is requested as it is believed to place the application in better condition for appeal, without requiring extension of the field of search.

If an extension of time for this paper is required, petition for extension is herewith made.

Applicant: BONUTTI, Peter M.
Application No.: 10/775,996
Examiner: Hoffman, Mary C.

No fee is believed due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 50-3410 (Docket No. 780-A03-021-5).

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Paul Bianco', with a stylized flourish at the end.

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